厚生労働省科学研究補助金
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平成２１年度～平成２３年度
総合研究報告書

バイオニック血圧制御システムの実用化開発
（Ｈ２１－トランス－一般－０１３）

主任研究者：砂川　賢二
（九州大学大学院医学研究院）

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研究代表者　砂川　賢二（九州大学大学院医学研究院循環器内科　教授）

研究要旨:
研究の目的・必要性・背景:医学の進歩により代表的な血圧調節失調である高血圧は薬剤治療が可能になってきた。しかしながら、圧反射システムそのものが破綻する血管運動中枢の機能不全（全身麻酔、変性性疾患）、圧受容器の障害（腫瘍による手術、放射線治療、外傷）や脊髄損傷（外傷、変性疾患）による血圧失調に有効な治療戦略は皆無である。これらの病態では、患者は重篤な体位性低血圧をおこしQOLのみならず易感染性のため生命予後は著しく悪化する。申請者は人工血管運動中枢（バイオニックブレイン）を自律神経系と融合させることにより、圧反射機能を再建するバイオニック血圧制御システムを世界で初めて実現した。バイオニック血圧制御システムは申請者が代表を務める先端医療開発特区（スーパー特区）「日本発の独創的な技術に基づいた情報型先進治療システム」のコアプロジェクトとして基盤研究が推進されている。本研究は当該開発を飛躍的に加速し、実用化するための前臨床試験・臨床試験を行うことを目標にする。
期待される成果:（1）脊損患者の血圧制御システム:治療不能であった重篤な体位性低血圧を予防することで、QOL の改善のみならず、易感染性から脱却でき生命予後の改善が可能。社会的な影響は極めて大きい。（2）術中血圧制御システム:麻酔中の潜在的な中枢性血圧失調のため、少量の出血や静脈への血液プーリングにより術中は急激な低血圧を起こす。バイオニックシステムによる術中の低血圧の防止は安全安心医療に大きく貢献する。技術立国を目指す我が国にとって、これらの我が国発の世界最先端の医療技術を駆使した治療機器の実用化は、医療機器産業の活性化および人材育成に直結し、長期的な経済的・社会的な効果は極めて大きいと考える。
研究計画・方法:（1）脊損患者の血圧制御システム:バイオニック血圧制御システムにより脊損患者の体位性低血圧を克服する基盤技術は既に開発されている。実用化には経皮的電気刺激条件の最適化(用量探索試験)、瞬時血圧測定システム開発、バイオニックブレインによる制御論理の最適化、車いすを含めた統合システム開発、安全性試験が必要である。これらの開発と共に、企業と連携して期間内に前臨床試験・臨床試験を行う。（2）術中血圧制御システム:バイオニック血圧制御システムにより術中血圧を安定化させる基盤技術はすでに開発されている。実用化には硬膜外電極による脊髄刺激条件の最適化(用量探索試験)、制御論理の最適化、全体のシステム化、安全性試験が必要である。これらの開発と共に、期間内に企業と連携して前臨床試験および臨床試験を行う。
研究結果（1）脊損患者の血圧制御システム:広範囲の皮膚刺激に応じて血圧は変化した。最終仕様として、下腹部を中心に刺激を行うこととした。刺激条件の詳細に関しては、知財やビジネス戦略に直結するので、詳細は割愛する。制御は、固定パラメター方式でも、robust な制御ができることが明らかになった。しかしながら、実環境で使用された場合を考慮すると、さらなる頑健な制御論理を必要するものと思われた。（2）術中血圧制御システム:ヒトの血管運動性交感神経を刺激する方法として，硬膜外カテーテル電極を用いた方法を採用した。本年度は全身麻酔中の患者を対象に，硬膜外腔からの電気刺激に対する動脈圧応答を伝達関数として同定し、制御理論を開発した。術中低血圧モデルにおける有効性を明らかにすることができた。
倫理面への配慮:企業との共同研究は九州大学臨床研究利益相反マネージメント委員会の承認を受ける。本開発に必要な動物実験は、九州大学・高知大学では大学動物実験審査委員会の承認を受け、国立循環器病研究センターでは厚生労働省の所管する実施機関における動物実験等の実施に関する基本指針に従って動物実験委員会の承認を受け行う。臨床試験は、各々の施設で倫理審査委員会の承認を受けた後、ボランティアの完全な自由意思による同意に基づき、書面でのインフォームドコンセントを得て行う。

A.研究目的

医学の進歩により代表的な血圧調節失調である高血圧は薬剤治療が可能になってきた。しかしながら、圧反射システムそのものが破綻する血管運動中枢の機能不全、圧受容器の障害や脊髄損傷(外傷、変性疾患)による血圧失調に有効な治療戦略は皆無である。これらの病態では、患者は重篤な体位性低血圧をおこし QOL の低下みならず易感染性のため生命予後は著しく悪化する。申請者は人工血管運動中枢(バイオニックブレイン)を自律神経系と融合させることにより、圧反射機能を再建するバイオニック血圧制御システム(図 1)を世界で初めて実現した。バイオニック血圧制御システムは申請者が代表を務める先端医療開発特区(スーパー特区、H20 年度)『日本発の独創的な技術に基づいた情報型先進治療システム』のコアプロジェクトとして基盤研究が推進されている。本研究は、この基盤研究に基づき①脊損患者の血圧制御システム、および②術中血圧制御システムを実用化するための前臨床試験・臨床試験を行うことを目標にする。

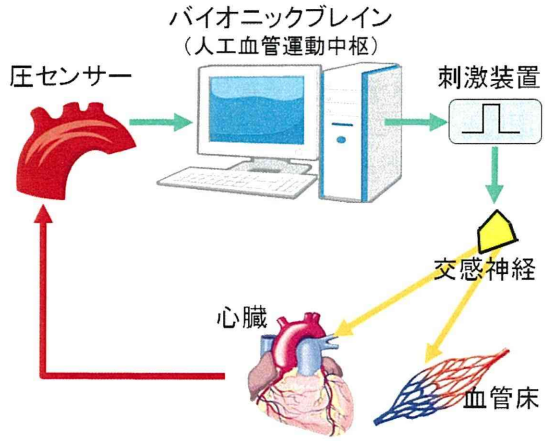

図 1 バイオニック血圧制御システムの構成図

B. 研究方法

- 脊損患者の血圧制御システム:バイオニック血圧制御システムにより脊損患者の体位性低血圧を克服する基盤技術は既に開発されている。実用化に向けて経皮的電気刺激条件の最適化(用量探索試験)、瞬時血圧測定システム開発、バイオニックブレインによる制御論理の最適化を行う。企業と連携して期間内に前臨床試験・臨床試験を行う。
- 術中血圧制御システム:バイオニック血圧制御システムにより術中血圧を安定化させる基盤技術は、申請者等によりすでに開発されている。実用化のために硬膜外電極による脊髄刺激条件の最適化(用量探索試験)、制御論理の最適化を行う。全体のシステム化(2 次試作)を行い、安全性試験を行う。企業と連携して前臨床試験・臨床試験を行う。

C. 研究結果

- 脊損患者の血圧制御システム:経皮的電気刺激条件の最適化を行った。間歇刺激をすることで神経刺激の慣れ現象を克服することができた。制御を適切に行うために血圧応答の動的特性を推定し、そのモデル化を行った。生体応答は一次遅れの系で近似できることが分かった。それに基づき制御システムの設計が可能になった。制御に不可欠な瞬時血圧を足背動脈から容積補償法で測定することができることが示された。
- 術中血圧制御システム: 圧反射失調の臨床的モデルとなる全身麻酔中の患者を対象に,硬膜外腔からの電気刺激に対する動脈圧応答を伝達関数として同定し、また、硬膜外カテーテル電極の留置をより安全に行うため、カテーテルの経皮的挿入時に電極間インピーダンスを測定しながら電極留置位置を推測することが可能な装置を試作した。試作した装置を用いて術中低血圧モデルにおける有効性をあきらかにした。

D. 考察

- 脊損患者の血圧制御システム:治療不能であった重篤な体位性低血圧を予防することで、QOL の著しい改善のみならず、易感染性(誤嚥性肺炎等)から脱却でき生命予後の改善が期待される。社会的な影響は極めて大きい。二次試作システムも完成しており、臨床試験でも有用性が証明されている。今後は PMDA と相談を繰り返し、臨床治験を実施し実用化したい。
- 術中血圧制御システム:麻酔中の潜在的な中枢性血圧失調のため、少量の出血や静脈への血液プーリングにより術中は急激な低血圧を起こす。バイオニックシステムによる術中の低血圧の防止は安全安心医療に大きく貢献する。二次試作システムも完成しており、臨床試験でも有用性が証明されている。今後は PMDA と相談を繰り返し、臨床治験を実施し実用化したい。
- 波及効果:技術立国を目指す我が国にとって、我が国発の世界最先端の医療技術を駆使した治療機器の実用化は、医療機器産業の活性化および人材育成に直結し、長期的な経済的・社会的な効果は極めて大きいと考える。
- **倫理面への配慮**
  企業との共同研究は九州大学臨床研究利益相反マネージメント委員会の承認を受ける。本開発に必要な動物実験は、九州大学・高知大学では大学動物実験審査委員会の承認を受け、国立循環器病研究センターでは厚生労働省の所管する実施機関における動物実験等の実施に関する基本指針に従って動物実験委員会の承認を受け行う。First in man 臨床試験は、各々の施設で倫理審査委員会の承認を受けた後、ボランティアの完全な自由意思による同意に基づき、書面でのインフォームドコンセントを得て行った。

E.結論

バイオニック医学の枠組みは、臨床例においても有効に機能することが示された。今後は試作装置を基盤にPMDAとの治験相談を行い、早期の実用化を目指す。

F. 健康危険情報

なし

G.研究発表

G-1.論文

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